Dissenting Views to H.R. 2505
"Human Cloning Prohibition Act of 2001"

We strongly dissent from H.R. 2505 as reported by the Judiciary Committee. We agree that human cloning – the production of children genetically identical to existing or previously existing human beings – is unsafe and unethical and should be prohibited. However, we believe that manner in which H.R. 2505 is written would extend the bill's prohibitions far beyond the goal of banning human cloning and would prevent our citizens from benefitting from ongoing or prospective stem cell research.

The bill before us is so sweeping that it would not only ban reproductive cloning, but all uses of nuclear transfer – also known as therapeutic cloning – for research or medical treatment. This would block treatments designed to help persons suffering from Alzheimer's, diabetes, stroke, Parkinson's disease, heart disease, or spinal cord injury, to name but a few. If this bill passes into law, it would ban those stem cell treatments that would be most effective and that would not require the use of dangerous immunosuppressive drugs. The bill is so broadly written that it bans the importation of lifesaving medicines from other countries if their production is in any way derived from nuclear transfer. This means that if another nation's scientists used stem cell research to develop a cure for cancer, it might be illegal for persons living in this country to benefit from the drug. In addition, the legislation could operate to ban legal and unobjectionable infertility treatments.

It is for these reasons that the legislation is opposed by numerous national organizations that represent patients, such as the National AIDS Treatment Advocacy Project, the Coalition of National Cancer Cooperative Groups, the National Patient Advocate Foundation, the Alliance for Aging Research, the American Infertility Association, the Juvenile Diabetes Research Foundation International, the Lymphoma Research Foundation of America, and the Society for Women's Health Research. The legislation is also strongly opposed by a wide variety of medical researchers, including the American Association for Cancer Research, the American Liver Foundation, the American Physiological Society, the Biotechnology Industry Organization, the Kidney Cancer Foundation, the American Society for Reproductive Medicine, and the Federation of American Societies for Experimental Biology.[1]

Summary of Legislation and Democratic Concerns

[1]Letter From 43 Organizations and One Individual to Speaker Dennis Hastert (July 23, 2001) (on file with the minority staff of the House Judiciary Committee) [hereinafter "Patients' Letter"]; Letter from Dr. Robert R. Rich, President, Federation of American Societies for Experimental Biology, to Ranking Member Conyers (July 23, 2001) (on file with the minority staff of the House Judiciary Committee) [hereinafter "FASEB Letter"].

H.R. 2505 makes human somatic cell nuclear transfer into an egg a federal felony. This process consists of removing or inactivating the nuclear material of an egg and transferring into the egg the nuclear material and DNA from one or more human somatic cells (cells with the full complement of genes). There is no requirement that the transfer produce a child. The bill therefore criminalizes a scientific research process that takes place in a petri dish, regardless of the intent of the researcher or of the inability for this process to result in the birth of a cloned child.[2] The penalty for violating these provisions includes sanctions of a criminal fine and/or imprisonment for up to ten years, and a civil penalty of at least $1 million.[3]

Additionally, the bill makes it unlawful knowingly to attempt to perform nuclear transfer, to participate in such an attempt, or to ship, receive, or import for any purpose the embryos produced by nuclear transfer or products derived from such embryos. The importation of such products is prohibited regardless of whether they are capable of developing into a full human being; an American with an otherwise incurable disease therefore would be prohibited from importing a stem cell treatment developed abroad, where nuclear transfer research might be protected, if the stem cells were in any way derived from therapeutically cloned embryos.[4]

By imposing these prohibitions, the bill would extend the reach of the criminal law into areas of pure scientific research. Currently, the federal government attempts to shape scientific research mainly through conditions on federal funding. Making a federal felony of somatic cell nuclear transfer (which takes place entirely in a petri dish, with no human or animal subjects) would represent an unprecedented intrusion of the criminal law into the scientific process and would constrain the influence of the National Institutes of Health in the funding of stem cell research.

If H.R. 2505 were to pass into law in its present form it would be difficult, if not impossible, for our nation to benefit from stem cell research that is currently ongoing or that would take place in the future. This is because the only practical means of developing breakthroughs in stem cell research into treatments is though the use of somatic cell nuclear transfer. The bill prohibits the importation of safe and effective medical treatments, and it would use the criminal law to interfere with the scientific process

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[2]The bill contains a "scientific research" exception for the use of cloning techniques to produce copies of DNA, tissues, organs, plants, or animals other than humans, but the research uses of nuclear transfer remain forbidden. Even if the oocyte had been modified so that it could not develop into a full human being, it would still be illegal to perform the transfer.

[3]In cases involving a pecuniary gain, the civil penalty is to be no less than $1 million and no more than twice the gross gain, if that sum exceeds $1 million.

[4]This broad prohibition on the import of medical treatments was not present in the original version of the bill, H.R. 1644.

and with advanced infertility treatments. For these and the reasons set forth herein, we dissent from the legislation.

I. Democrats Would Support a Ban on Human Cloning, But H.R. 2505 Goes Too Far

This Congress can and should outlaw the practice of human cloning. Experiments in animal cloning have revealed exceptionally high rates of deformities and birth defects, and the use of this procedure in humans has been almost unanimously rejected by the scientific community as unsafe to both mother and child.[5] Beyond issues of safety, using human cloning to produce a child would raise significant ethical problems, bringing the status of the child into question and raising severe dangers of abuse.[6] No pressing need exists to allow such cloning, and we believe it is appropriate for Congress to make the practice illegal. This is why at markup, Democrats unanimously voted in favor of the Schiff substitute – based on the Greenwood/Deutsch legislation[7] – which would have, among other things, focused the bill on reproductive cloning and banned the implantation of a cloned embryo. Unfortunately, the Schiff substitute was defeated on a party-line vote.

By contrast, we cannot support the overbroad approach taken by H.R. 2505. A ban on human cloning does not need to include a ban on nuclear transfer research. The former brings a new child into the world; the latter is concerned only with the study of embryonic development and the curing of disease. The majority has argued that such research lies on a "slippery slope" that leads to reproductive cloning and beyond; but there is no sense in which reproductive cloning is the logical "next step" after nuclear transfer research. Nothing links the pursuit of stem-cell research to the deliberate

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[5]*See generally Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and* Commerce, 107th Cong. (2001) (statements of Mark E. Westhusin, Associate Professor, Texas A&M University, and Rudolf Jaenisch, Professor of Biology, Massachusetts Institute of Technology); Rudolf Jaenisch and Ian Wilmut, *Don't Clone Humans!*, 291 SCIENCE at 2552 (March 30, 2001); FASEB Letter, at 1. To date, the only intentions to clone human beings have been expressed by a small number of groups and individuals far from the mainstream of the scientific community. *Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and* Commerce, 107th Cong. (2001) (statement of Rael, leader of the Raelian movement).

[6]A child who has the exact genetic makeup of another would have an unclear status under family law, and the attempt to duplicate an existing person would severely compromise the individuality of the cloned child. Additionally, human cloning might be misused by parents, who might place expectations on a cloned child's future (e.g., if the child is the clone of a basketball star).

[7]H.R. 2608.

creation of human beings. Even if such a link existed, Congress would still be perfectly capable of saying "this far, and no further."

The technique of *in vitro* fertilization has not brought the elimination of parenthood and the armies of test-tube babies that were originally feared; instead, it has allowed for millions of Americans to do what they were once told was impossible – to have a child of their own. In the same way, Congress can permit nuclear transfer research without accepting as necessary consequences the worst fears of its critics.

The majority has also argued that a ban on reproductive cloning alone would be unenforceable. However, it has not for a moment explained how the government could enforce the prohibitions in H.R. 2505. Anyone who is willing to break the law to clone a child will surely be willing to break the law to create an embryo. If a ban on the surgical procedure of implanting embryos into the uterus is unenforceable, a ban on a procedure that takes place in a petri dish in the privacy of a scientific laboratory is even more so. The process of nuclear transfer is relatively simple, and the embryos it creates are indistinguishable in all respects (except for their genetic makeup) from embryos created through *in vitro* fertilization. As Dr. Panos Michael Zavos testified, the technology to conduct nuclear transfer exists "in every IVF high-tech laboratory across the world," 55 of which are located in New York City alone.[8]

Without putting police in the laboratory, there is no way for the government to prevent in advance an individual bent on violating the law; it can only rely on the deterrent effect of criminal penalties should the violation become known. The steps of implantation and gestation and the birth of a cloned child would clearly alert law enforcement to the violation, and a prohibition narrowly focused on reproductive cloning would provide the needed deterrent. Moreover, because H.R. 2505 lacks any prohibition on the implantation of a cloned embryo into a woman's uterus, under its terms law enforcement would be helpless to prevent human cloning after the embryo stage. As a result, a narrowly focused ban would be just as effective in preventing human cloning, but would not have the unfortunate consequence of criminalizing lifesaving research.

II. H.R. 2505 Would Prevent Lifesaving Research in the United States

The understanding of the workings of stem cells – the flexible cells that regenerate the body's tissue[9] – has advanced dramatically since 1998, when J.A. Thompson and other scientists first isolated

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[8] *Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and* Commerce, 107th Cong. (2001) (statement of Dr. Panos Michael Zavos).

[9] "A stem cell is a special kind of cell that has a unique capacity to renew itself and to give rise to specialized cell types. Although most cells of the body, such as heart cells or skin cells, are

stem cells from human embryos.[10] These undifferentiated cells[11] are the body's jacks-of-all-trades; they have the unique ability to become any kind of tissue found in the body – anything from blood or bone to nerves and heart muscles. As a result, embryonic stem cells offer immense potential to treat what have been thought to be incurable conditions by replacing the body's damaged tissue with healthy new cells.

In its recent report on the uses of stem cells, the National Institutes of Health described their medical potential as "enormous."[12] It concluded that transplants of stem cells could be used to treat conditions as varied as Parkinson's disease, chronic heart disease, end-stage kidney disease, and liver failure.[13] Rheumatoid arthritis, osteoporosis, and severe burns might all find new treatments.[14] Stem cells could repair damage to the nervous system from spinal cord injury, multiple sclerosis, and Alzheimer's.[15] Insulin-producing cells could be introduced to treat diabetes.[16] Brain damage due to

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committed to conduct a specific function, a stem cell is uncommitted and remains uncommitted, until it receives a signal to develop into a specialized cell. Their proliferative capacity combined with the ability to become specialized makes stem cells unique." National Institutes of Health, Stem Cells: Scientific Progress and Future Research Directions (June 2001) [hereinafter "NIH Report"], at ES-1. Stem cells can be derived from any embryo, whether created from sexual (*e.g.*, *in vitro* fertilization) or asexual (*e.g.*, nuclear transfer) reproduction.

[10]J.A. Thompson *et al.*, *Embryonic stem cell lines derived from human blastocysts*, 282 SCIENCE 1145-7 (1998).

[11]Soon after the embryo is implanted in a woman's uterus, its cells begin to differentiate, changing their form to match the function they will perform in the fetus. Some will become muscle cells, others nerve cells, others skin cells. Embryonic stem cells are the original cells that have not yet differentiated and chosen their function; they therefore hold the potential to repair any of the body's organs.

[12]NIH Report, at 66.

[13]NIH Report, at ES-4.

[14]NIH Report, at 65; Robert P. Lanza *et al.*, *The Ethical Validity of Using Nuclear Transfer in Human Transplantiation*, 284 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 3715 (Dec. 27, 2000) [hereinafter "Lanza *et al*."].

[15]*Id*.

[16]Stem cells could be used to treat diabetes by replacing the damaged insulin-producing cells of the pancreas. The discovery of a stem-cell treatment for diabetes, for which there is currently no cure, would be a significant advance:

stroke could be reduced or reversed.[17] Replacement therapies could be created for autoimmune diseases such as lupus.[18] Survivors of heart attacks could be given healthy cardiovascular cells to heal damaged heart tissue and restore them to health.[19] Cancer patients who undergo severe chemotherapy could receive stem cell transplants to restore their blood cells and immune systems – and specialized new treatments could be developed to target and destroy individual cancer cells.[20] New treatments could even be discovered to restore function to paralyzed limbs, or to treat the degeneration caused by ALS (also known as Lou Gehrig's disease).[21] Finally, some have held out the hope of generating entire transplantable organs (bones, kidneys, and even hearts) through stem cell research.[22]

Nuclear transfer research of the type banned by H.R. 2505 would be at the foundation of any medical treatment that took advantage of these discoveries. Like all transplants, stem cell treatments run the risk of being rejected by the patient's immune system. In fact, because stem cell transplants are so limited, they would be easy for the immune system to overwhelm. In its report, the NIH noted that there is a "very high" potential for immune rejection of these transplants; "Modifications to the cells, to

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> Each year, diabetes affects more people and causes more deaths than breast cancer and AIDS combined. Diabetes is the seventh leading cause of death in the United States today, with nearly 200,000 deaths reported each year. The American Diabetes Association estimates that nearly 16 million people, or 5.9 percent of the United States population, currently have diabetes. (NIH Report, at 67.)

[17]NIH Report, at 77. The Report states that "Just a decade ago, neuroscience textbooks held that neurons in the adult human brain and spinal cord could not regenerate. Once dead, it was thought, central nervous system neurons were gone for good." New research and the possibilities of stem cell treatments promise to reverse that long-held medical dogma. *Id*.

[18]NIH Report, at 62. The Report notes that lupus, a disease in which the immune system attacks the body's own cells, affects more than 239,000 Americans, over 90 percent of whom are women. African-American and Hispanic women are disproportionately affected. Currently, no treatment exists for the disease. *Id*.

[19]NIH Report, at 87. Today, more than 4.8 million Americans suffer from congestive heart failure, with 400,000 new cases each year. Nearly 1.1 million Americans a year suffer from heart attacks. Stem cell treatments to repair the heart and circulatory system could therefore target "a major cause of death and disability in the United States." *Id*.

[20]NIH Report, at ES-5.

[21]NIH Report, at 79.

[22]Lanza *et al*., at 3715.

the immune system, or both will be a major requirement for their use."[23] However, the NIH also found that if the stem cells were obtained from embryos produced by somatic cell nuclear transfer, they would bear the patient's DNA and would appear to the patient's body like his or her own cells, removing the risk of immune rejection. The transplant could then take place without the use of dangerous immunosuppressive drugs – "a labor intensive, but truly customized therapy."[24] Nuclear transfer techniques are vital to realizing the potential of stem cell treatments and moving the science from the petri dish to the doctor's office.

H.R. 2505 goes beyond banning reproductive cloning to ban research in somatic cell nuclear transfer. The result is that the bill would cut off scientific developments that are granting new hope to millions of Americans who have been told there is no cure. Without the use of nuclear transfer, these stem cell developments will likely remain in the laboratory and will not be used to help patients.

By banning nuclear transfer techniques, H.R. 2505 would also cut off research in new areas of regenerative medicine. As researcher Thomas Okarma testified before the Subcommittee on Crime, it may soon be possible to turn a differentiated cell (such as a skin cell) back into an undifferentiated state, essentially creating compatible stem cells from the patient's own body. This procedure would avoid any need to use nuclear transfer and would not involve embryos in any way, offering the possibility of new medical treatments that would avoid the controversies that have accompanied stem-cell research. However, Okarma testified that some nuclear transfer research will be "essential" for the early stages of understanding how stem cells gain their flexibility, and would be "a critical step to improve the usefulness of adult stem cells" as well.[25] Nuclear transfer research would also provide a greater understanding of embryonic development that could be used to determine the causes of (and perhaps to prevent) birth defects, miscarriages, and juvenile diabetes.[26] The Federation of American Societies for Experimental Biology has echoed the NIH's language in describing such research: "The potential for treating human disease in this exciting area of regenerative medicine is enormous."[27] However, all of these promising advances would be blocked by H.R. 2505.

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[23]NIH Report, at ES-5.

[24]NIH Report, at 17.

[25]*Human Cloning: Hearings on H.R. 1644 and H.R. 2172 Before the House Subcomm. on Crime*, 107th Cong. (2001) (Statement of Thomas Okarma, CEO of Geron, Inc.).

[26]*Id*.

[27]FASEB Letter, at 2.

The majority has sought to establish that the use of embryonic or cloned stem cells would be unethical when an alternative, namely adult stem cells, is available.[28] However, the studies necessary for regenerative medicine could not be accomplished with adult stem cells. Additionally, after surveying the current state of the science, the NIH concluded that embryonic stem cells have important advantages over adult stem cells: the latter cannot develop into as many different cell types; they cannot be generated in the same quantities in the laboratory; and they are difficult and sometimes dangerous to extract from an adult patient (especially stem cells located in the brain).[29] Given the very real benefits that this research could hold for those suffering Americans who are already living, it is appropriate for Congress at the very least to permit such research to go on in the private sector.[30]

Unfortunately, H.R. 2505 would prohibit this valuable research and leave no viable alternative, and it would do so permanently. At the markup, the majority claimed that as the science progresses,

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[28]*The Ethics of Human Cloning: Hearing Before the House Subcomm. on Crime*, 107th Cong. (2001) (Statement of David Prentice, Professor of Life Sciences, Indiana State University). Cells with similar properties known as "embryonic germ cells" can also be obtained from aborted fetuses, but these will not necessarily be compatible with the patient's immune system. Furthermore, their source of origin makes them no less controversial to the majority.

[29]NIH Report, at ES-9-10. It is important to note that at the stage when embryonic stem-cell research normally occurs, the embryos are less than 14 days old and consist of a tiny ball of undifferentiated cells, without organs or internal structure, let alone a nervous system, nerve impulses, feelings, or the capacity to feel pain. Even in the womb, the great majority of early embryos – as many as 80 percent – never develop into a human being. Furthermore, the separation of an embryo into twins or triplets frequently does not occur until after this stage of development, implying that the embryos cannot meaningfully be ascribed personal identity, uniqueness, or individuality. Lanza *et al*. As a number of prominent scientists and bioethicists have agreed, "The line established by gastrulation and the appearance of the primitive streak is a clear one, as is the line between therapeutic and reproductive cloning." *Id.* Even anti-choice Sen. Orrin Hatch has indicated that one should not equate a fetus in the womb, "with moving toes and fingers and a beating heart, with an embryo in a freezer." Sheryl Gay Stolberg, *Morality and Medicine: Reconsidering Embryo Research*, N.Y. TIMES (July 1, 2001), sec. 4, at 1. Great Britain has permitted research involving embryos since 1990, and no abuse of research involving human subjects has occurred, nor has anyone suggested that it should. Lanza *et al*.

[30]As Ronald M. Green, director of the Ethics Institute at Dartmouth College and former president of the Society of Christian Ethics, wrote to the Committee, H.R. 2505 should be rejected because it would go beyond a ban on human cloning to "prohibit several other very research directions of possibly great medical benefit." *See* Letter from Ronald M. Green to Chairman Sensenbrenner and Ranking Member Conyers (July 23, 2001) (on file with the minority staff of the House Judiciary Committee) [hereinafter "Green Letter"].

researchers might convince a future Congress to repeal the research prohibition.[31] But Congress should never establish a permanent criminal prohibition with an eye towards repealing it a few years later. Biomedical research progresses at an amazing speed; indeed, human pluripotent stem cells were first isolated in November 1998. Further advances are occurring at a dizzying pace, and a complete medical revolution may well occur within the next five years. Yet the maximum penalty for conducting nuclear transfer research under H.R. 2505 is ten years imprisonment. Legalizing nuclear transfer research after its potential has been realized would bring about the absurd result that the prison sentences would outlast the prohibitions – that scientists who practice nuclear transfer after its legalization would be hailed as miracle workers and perhaps even afforded federal funding, while their colleagues who first pioneered the techniques would still be in jail.

It is unclear how the effectiveness of nuclear transfer could be demonstrated to the majority's satisfaction. We already have significant evidence regarding the potential of embryonic or cloned stem cells from animal research. While research involving human embryonic stem cells might continue (although slowly, if the President chooses to deny federal funding to such research and push it into the private sector), there will be no evidence regarding the effectiveness or suitability for testing of human stem cells obtained through nuclear transfer. We will never know what results might have been obtained had nuclear transfer research been legal, and if a permanent ban is placed on the research, we will never know enough to justify its decriminalization in the majority's eyes.

III. H.R. 2505 Would Prevent U.S. Citizens From Benefitting From Lifesaving Research Performed Abroad

We also cannot support H.R. 2505 because the shipping, receipt and importation provisions are overbroad and would block Americans' access to lifesaving medical treatments produced abroad. In the original version of the bill, these provisions prohibited only the shipping, receipt or importation of cloned embryos – a prohibition, if too expansive, at least reasonably related to the bill's flawed definition of human cloning. However, the new provisions inserted in H.R. 2505 would block not only the importation of cloned embryos, but also of any product "derived" from such embryos, even if these products (such as stem cell-grown nerve tissue to restore paralyzed limbs) were unable to develop into a full human being. Moreover, since the critical term "derived" is not in any way elaborated on, under a plausible "fruits-of-the-tree" doctrine, the bill might even ban the importation of synthetic medicines modeled on proteins originally derived through this process.

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[31]This argument was made by Rep. Smith when the Majority rejected a Scott amendment to provide for a 5-year sunset as recommend by the National Bioethics Advisory Commission. The argument was also made by the Majority's witness at our hearings. *Human Cloning: Hearings on H.R. 1644 and H.R. 2172 Before the House Subcomm. on Crime*, 107th Cong. (2001) (Statement of Alexander M. Capron, member of the National Bioethics Advisory Commission).

Representative Scott unsuccessfully offered an amendment to create an exemption for the shipping, receipt or importation of products to be used in medical treatment. Products that entered the country under this amendment would still have been required to undergo scrutiny by the Food and Drug Administration. Rejection of the Scott amendment clearly demonstrates that the legislation would keep safe and effective medical treatments out of the hands of U.S. citizens, even if the treatments have no chance whatsoever of being used for human cloning.

We fear that such a prohibition may have less to with human cloning than with elevating the status of an embryo above that of live-born human beings.[32] There is no risk that an American hospital might try to clone a human using stem cells from abroad. If researchers in Great Britain (where nuclear transfer research is legal and government-funded) were to discover a stem-cell-based cure for cancer, the majority would ban its importation simply because it was originally derived through nuclear transfer. In other words, the majority is willing to sacrifice the lives and health of millions of suffering Americans in order to protect frozen embryos or out of a vague fear that someone, somewhere, might perform human cloning. For a bill intended to protect our humanity, that rationale strikes us as somewhat ironic.

IV. H.R. 2505 Would Interfere With Stem Cell Research – Both Privately Funded and Funded by the National Institutes of Health

The legislation's proponents would have us believe H.R. 2505 has nothing to do with stem cell research and would not disrupt scientific advances being made in this important and much-discussed area. Nothing could be further from the truth.

There are several reasons why the legislation would interfere with and undermine stem cell research. First is the fact that stem cells can be derived from embryos created by both sexual and asexual (*e.g.*, nuclear transfer) means. As a basic and fundamental matter, by banning all forms of asexual reproduction based on cell nuclear transfer, the legislation would quite obviously limit stem cell research. It goes without saying that it will be more difficult to conduct stem cell research if one of the most promising techniques for developing stem cells -- therapeutic cloning – is criminalized.

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[32]The only argument offered by the majority in defense of these provisions was that an exemption for medical treatment might provide a financial incentive to create more embryos through nuclear transfer. This argument is a red herring. If a British university discovers a cure for cancer or diabetes that relies on stem-cell research, it will have quite enough of a financial incentive already. Additionally, the absolute number of embryos should be irrelevant. If the majority holds that legalizing nuclear transfer in the U.S. will make a ban on human cloning unenforceable, the same should hold true in Britain, and anyone who wishes to perform human cloning can simply travel there. Extra incentives to discover a cure for a terrible disease will not make the birth of a cloned child any more likely – they will only hasten the day when a cure arrives.

Second, if research were performed based solely on stem cells derived from sexual means (such as additional embryos formed through *in vitro* fertilization), it will be difficult to derive any practical benefit from the research without the benefit of nuclear transfer. If a scientist were to use IVF-derived stem cells to design a treatment for Alzheimer's disease, it still could not easily be applied to any patients without the utilization of therapeutic cloning. This is because, as we have noted above, scientists can greatly reduce the risk of immune rejection if we use stem cells which bear a patient's own DNA derived from therapeutic cloning rather than adult stem cells.

This conclusion is supported by the NIH in their July 18, 2001, study finding that embryonic stem cells have important advantages over adult stem cells. The NIH recognized that adult stem cells cannot develop into as many different cell types; they cannot be generated in the same quantities in the laboratory; and they are difficult and sometimes dangerous to extract. It is also critical to note that the NIH has specifically stated that somatic cell nuclear transfer would be a "truly customized" way of creating stem cell transplants that would not be rejected by the body's immune system.[33]

Third, although the NIH does not presently conduct research using human somatic cells, that decision has been made voluntarily by scientists and the executive branch, not statutorily by Congress. By passing a one-size fits all ban, we will permanently and inflexibly ban the practice, tying the hands of future scientists and the Administration alike. This is in direct contradiction of the NIH's own conclusion that it is premature to discard the potential benefits of new forms of stem cell research.[34]

Fourth, because the legislation prohibits the shipping, receipt, or importation of embryos produced abroad by nuclear transfer or of products derived from such embryos, NIH would not be able to benefit from many forms of research conducted abroad involving stem cells. This would put our own scientists at a distinct disadvantage compared to other nations' researchers in the race to develop cures for crippling and fatal diseases. At present there is no law which prevents the NIH from acquiring foreign products in any way derived from therapeutic cloning techniques. H.R. 2505, however, provides an inflexible and permanent ban which restricts our own Administration.

Finally, if the majority did not believe that the bill would undermine stem cell research, they would have had little reason to reject the Lofgren-Conyers amendment exempting stem cell research from the bill's prohibitions. If we truly want to insure that stem cell research is not interrupted, we would carve the activity from out of the bill's reach. However, the majority rejected this notion, in a straight party-line vote.

V. H.R. 2505 Would Ban Legal and Unobjectionable Infertility Treatments and Techniques of *In Vitro* Fertilization

[33]NIH Report, at 17.

[34]NIH Report, at ES-10.

H.R. 2505 further exceeds its mandate to prohibit human cloning by bringing the heavy penalties of the criminal law to bear on infertility treatments that have nothing to do with human cloning. Over the past four years, the process of "ooplasmic transfer" has been used in connection with *in vitro* fertilization to help more than 30 infertile couples conceive a healthy child.[35] The process involves the replacement of some of the cytoplasm (the fluid that constitutes the bulk of a cell) in an infertile woman's egg with cytoplasm from a healthy donor egg or other cell. The original egg has been fertilized with genetic material from the husband and will develop normally, thanks to the infusion of healthy cytoplasm.

However, the definition of "human cloning" in H.R. 2505 is so overbroad as to likely ban this procedure. The bill includes under the definition the introduction of any "nuclear material" from "one or more human somatic cells" into an egg whose nuclear material has been removed or inactivated. Yet the technique described above (and possibly other techniques of *in vitro* fertilization as well) could introduce into the fertilized egg some of the donor cell's mitochondria, the "power plants" that float in the cytoplasm and generate energy for the cell. Mitochondria are unique because they have their own DNA and reproduce on their own. Thus, the introduction of mitochondria from a healthy, mature cell into a fertilized egg would yield a new organism that is genetically virtually identical to the pre-transfer egg, yet with slightly different mitochondrial DNA. It might therefore be considered to be "human cloning," even though the resulting child would have genes from both parents, and would bring 10-year jail sentences on the participants under H.R. 2505.

At the very least, a ban on this technique of *in vitro* fertilization is a plausible reading of H.R. 2505. However, when Representative Jackson-Lee offered an amendment to clarify the bill's intent and explicitly exempt *in vitro* fertilization and other fertility treatments from the prohibitions, it was defeated on a party-line vote.[36] Passage of H.R. 2505 without including a protection for *in vitro* fertilization runs the risk that future courts will find accepted and beneficial fertility treatments in violation of the criminal law, and that infertile couples will be denied a safe and effective means of conceiving children.

Conclusion

Because it far exceeds its mission of prohibiting human cloning, H.R. 2505 can be seen as an attempt to do secretly what the Administration would hesitate to do publicly: to ban the use of stem-cell-based treatments in the United States. If H.R. 2505 becomes law, it would be difficult, if not impossible, to derive any practical benefit from stem cell research, because we would be unable to implement its discoveries through nuclear transfer or therapeutic cloning.

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[35] *Infertility Treatment Leaves Kids With Extra DNA*, REUTERS (May 7, 2001).

[36] The amendment offered by Representative Schiff, which contained a similar exemption in its rule of construction, was also defeated.

Under H.R. 2505, the new discoveries and medical cures resulting from stem cells will be off-limits to Americans who cannot afford to travel abroad to countries where nuclear transfer research is still pursued. The production of such treatments would be prohibited domestically, and the importation of even a cancer cure from abroad would carry a 10-year prison sentence. Furthermore, the vagueness and overbreadth of H.R. 2505 run the risk of prohibiting legitimate and uncontroversial techniques of *in vitro* fertilization that could help thousands of couples conceive their own children. H.R. 2505 represents far more than a ban on human cloning: it represents an intrusion of the criminal law into the research process, and it should be rejected.

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